UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,970	01/03/2001	Hideaki Nomura	081356/0156	8299

22428 7590 10/27/2004

FOLEY AND LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 10/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/720,970	NOMURA ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,13,14,16-20,24 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,13,14,16-20,24 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Amendments/Remarks received on August 2, 2004 and the information Disclosure Statement received on April 16, 2004 is acknowledged. Claims **1-9, 13-14, 16-20, and 24-25** are pending in this application. Claims 10-12, 15, 22-23, and 29 stand cancelled. Claims 26-28 are withdrawn from prosecution.

Response to Amendment

The Rule 132 Declaration under 37 CFR 1.132 filed 8/2/04 is insufficient to overcome the rejection of claims over Norling et al since it does not provide factual evidence for assertions. However, the amendments of 8/2/04 to structurally define the claims overcomes Norling et al.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 13-14, 16-20, and 24-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is directed to drug that have a molecular weight of 1000 MW or greater. This limitation is indefinite since firstly it is unclear what the units MW refers to and secondly molecular weight is conventionally described in Daltons or kilo Daltons. Further, clarification is requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 7, 9, 13-14, 17, 20, and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cumming et al (6,153,220).

Cumming et al teach a taste-masked formulation containing a cationic copolymer (Eudragit E 100) and a drug in powder form. See Abstract and examples. Cumming teaches drugs such as peptides, proteins, and hormones in the composition. See column 3, lines 9-10. Several ratios are taught such as 1:1, 1:2, 1:10, etc. See Table 1. The composition may include conventional excipients (adjuvant). See examples.

Cummings does not exemplify the instant peptides or proteins in the composition.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Cumming and utilize the instant drugs in the composition. One would have been motivated to do so since Cumming teaches the suitability of proteins, peptides, and hormones as the active agent in a taste-masked composition. Therefore, one would be motivated to utilize a particular drug depending on the symptom to be treated. Note that

"proteins, peptides, and hormones" are characterized by a high molecular weight of greater than 1000 Daltons.

Response to Arguments

Applicant's arguments filed 8/2/04 have been fully considered but they are not persuasive.

Applicant argues that Cummings does not teach a medicine that is higher than 1000 MW. Applicant argues that the exemplified drugs are not the recited weight. Further, applicant argues that the proteins, peptides, and hormones disclosed in Cummings et al is not the instant molecular weight.

On page 6, of instant specification defines a high molecular weight as: "A medicine of high molecular weight" used in the invention refers to a bioactive peptide or protein, antibody, vaccine, antigen or the like. Moreover, dependent claim 7 and 17 recite "protein and peptides" as the high molecular weight drug without any specificity. Clearly, Cumming teaches instant drugs on column 3, lines 5-26. Secondly, disclosed examples or preferred embodiments, i.e. the use of low molecular drugs, do not constitute a teaching away from the broader disclosure, i.e. the use of proteins, peptides, etc. See *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971).

Applicant argues that Cummings is not analogous art. Applicant argues that Cumming does not address the problems associated with administering high molecular weight drugs into the mucosa. It is argued that Cumming does not address utilizing a methacrylate-based preparation for improving transmission of a high molecular drug through the mucosa.

Firstly, in response to applicant's argument that Cummings et al is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if

not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, applicant's invention is directed to a powder preparation comprising a medicine and Cummings et al is directed to a powder preparation comprising a medicine. Cummings et al and instant invention are directed to pharmaceutical art and thus Cummings is analogous art.

Secondly, the examiner again points out that the claims are directed to a *product.* Thus, the intended use of the product does not hold patentable weight unless it imparts a structural limitation; patentability lies with the product itself. Therefore, Cummings does not have to teach the instant administration. Secondly, in *product* claims, the prior art does not have to have the same reason for utilizing a certain polymer as the applicant since patentability lies with the product. Therefore, if the prior art comprises the instant polymer, then it is said to read on the instant invention.

Thus, for the reasons above, the rejection is maintained.

Claims 8 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cummings et al (6,153,220) in view of JP 406065090.

Cumming et al teach a taste-masked formulation containing a cationic copolymer (Eudragit E 100) and a drug in powder form. See Abstract and examples. Cumming teaches drugs such as peptides, proteins, and hormones in the composition. See column 3, lines 9-10. Several ratios are taught such as 1:1, 1:2, 1:10, etc. See Table 1. The composition may include conventional excipients (adjuvant). See examples.

Cummings et al do not specify G-CSF.

JP teaches G-CSF in a nasal formulation for curing leucopoenia.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Cummings et al and JP and utilize G-CSF. One would have been motivated to do so since JP teaches that the instant active treats leucopoenia. Further, one would be motivated to do so with the expectation of similar results since Cummings et al teach the suitability of proteins in the formulation and G-CSF is a protein. Therefore, one would have been motivated to utilize G-CSF in the formulation to treat leucopoenia.

Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cummings et al (6,153,220) in view of Stanton et al (5,807,552).

Cumming et al teach a taste-masked formulation containing a cationic copolymer (Eudragit E 100) and a drug in powder form. See Abstract and examples. Cumming teaches drugs such as peptides, proteins, and hormones in the composition. See column 3, lines 9-10. Several ratios are taught such as 1:1, 1:2, 1:10, etc. See Table 1. The composition may include conventional excipients (adjuvant). See examples.

Cummings et al do not specify a protein that is conjugated to a hapten.

Stanton et al teach the use of hapten-carrier (protein) molecules for use in human and animal prophylaxis. Stanton teaches the hapten-carrier molecules illicit immune response and functions as vaccine (col. 3, lines 10-40).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Cummings et al and Stanton et al and utilize a hapten conjugated protein. One would be motivated to do so since hapten-carrier (protein) molecules function as a vaccine as taught by Stanton et al. Further, one would have expected similar results

since Cummings teaches the suitability of proteins and peptides as the medicament of choice. Therefore, one would be motivated to incorporate a specific medicine depending on the symptoms to be treated or desired affect.

Claims 1-2, 6-7, 9, 13-14, 16-17, 20, 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sparks et al (5,354,556).

Sparks et al teach a controlled release powder and its preparation. The micro particles are in the form of a micrometric of an active ingredient uniformly distributed in a non-toxic polymer. See abstract. The polymer may be chosen from a variety of polymers and the preferable one is EUDRAGIT. See column 4, line 8 and examples. The polymers may also include a combination of polymers including instant hydroxypropyl methylcellulose. See column 3, lines 45-50. The spray dry solution may contain thickening agent such as xanthan gum. See column 6, lines 51-52. Suitable drugs such as insulin and glucagons for treating diabetes, both of which have a molecular weight of over 1000 Daltons, are taught. See column 5, line 9. The ratio of the drug to polymer may vary within the range of 0.1:10 to 10:1. See column 6 lines 20-22. The composition may have optional ingredients such as surfactants, active transport agents, etc. See column 7, lines 28-35.

Sparks does not exemplify the instant active agents.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Sparks et al and utilize the instant drugs in the composition. One would have been motivated to do so since Sparks teaches the suitability of insulin and glucagon, as the active agent in the composition. Therefore, one would have been motivated to utilize a particular drug depending on the symptom to be treated.

Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sparks et al (5,354,556) in view of MacCuish (5,674,845).

As set forth above, Sparks et al teach a controlled release powder and its preparation. The micro particles are in the form of a micrometric of an active ingredient uniformly distributed in a non-toxic polymer. See abstract. Suitable drugs include medicament that treat diabetes such as insulin and glucagons. See column 5, line 9.

Sparks does not specify the use of a hapten conjugated protein as the active.

MacCuish teaches treatment of insulin resistant diabetes. MacCuish teaches formulating IGF (insulin-like growth factor) for extended release in combination with hapten. The reference teaches the use of hapten with insulin as conventional. See column 2, lines 60-65.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Sparks et al and MacCuish et al and utilize a hapten conjugated protein. One would have been motivated to do so since MacCuish teaches the use of IGF conjugated to hapten to treat insulin resistant diabetes. Further, one would have a reasonable expectation of success since Sparks teaches the suitability of substances that treat diabetes. Therefore, one would have been motivated to utilize a particular drug depending on the symptom to be treated.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616

SSG

Gary L Kunz
GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600